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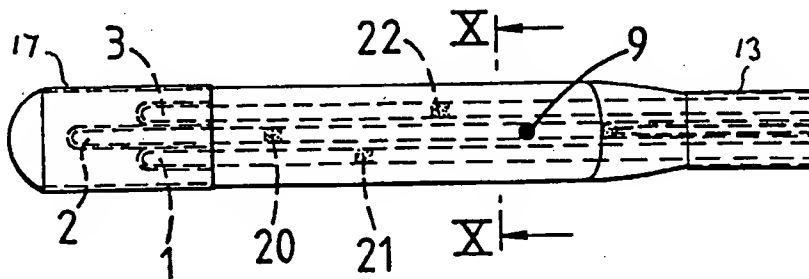
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/EP93/02774</p> <p>(22) International Filing Date: 7 October 1993 (07.10.93)</p> <p>(30) Priority data: 07/965,232 23 October 1992 (23.10.92) US</p> <p>(71) Applicants: OPTEX BIOMEDICAL, INC. [US/US]; 2202 Timberloch Place, Suite 220, The Woodlands, TX 77380 (US). LUCAS, Brian, Ronald [GB/GB]; 135 Westhall Road, Warlingham, Surrey CR6 9HJ (GB).</p> <p>(72) Inventors: KOSA, Nadhir, B. ; 2 Feather Branch Court, The Woodlands, TX 77381 (US). TWIGGS, Gene, J. ; 24511 Bridgewater, Magnolia, TX 77355 (US). SALTER, James, R. ; 18 North Deerfoot, The Woodlands, TX 77380 (US). SINGH, Raghuvir ; 109 E. Wavy Oak, The Woodlands, TX 77381 (US). COSTELLO, David, J. ; 22207 Sumac Lane, Spring, TX 77389 (US). SCHLAIN, Leslie, A. ; 12016 South Black Jack Oak, The Woodlands, TX 77380 (US).</p>	<p>(74) Agent: LUCAS, Brian, Ronald; Lucas & Co., 135 Westhall Road, Warlingham, Surrey CR3 9HJ (GB).</p> <p>(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	

(54) Title: METHOD OF MAKING AN OPTICAL FIBRE SENSOR PROBE



(57) Abstract

A method for making an optical fibre sensor probe, comprising the steps of: (a) taking one or more optical fibres (1, 2, 3) each having a bend therein, the fibre bend(s) disposed in a first section (6) at or adjacent a first end of the optical fibre sensor probe, the optical fibre probe having a second section (7) adjacent the first section (6), and a third section (8) adjacent the second section, (b) encapsulating the second section (7) of the optical fibre sensor probe in potting compound and curing the potting compound, ends of the optical fibre(s) (1, 2, 3) extending from the second section (7) and through the third section (8), (c) emplacing a first tube (13) over the third section (8) of the optical fibre sensor probe, and/or (d) emplacing a second tube (17) over the first section of the optical fibre sensor probe.

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METHOD OF MAKING AN OPTICAL FIBRE SENSOR PROBE

This invention relates to a method of making an optical fibre sensor probe and to an optical fibre sensor probe made by said method.

5 EP-A-0 232 369 discloses an optical fibre sensor probe which can be inserted into the arteries of a human being. In the embodiment disclosed a single parameter for example the partial pressure of oxygen or carbon dioxide in the blood can be monitored by passing light
10 through an optical fibre to a chemical indicator in a sample chamber and examining the light transmitted by the chemical and returned via a second optical fibre.

EP-A-0 530 262 discloses a method for making an optical fibre sensor probe which contains a multiplicity
15 of optical fibres, each associated with a separate sample chamber containing a chemical responsive to a separate parameter of the blood, for example the pH, or the partial pressure of carbon dioxide or oxygen.

According to one aspect of the present invention
20 there is provided a method for making an optical fibre sensor probe, which method comprises the steps of:-

(a) taking one or more optical fibres each having a bend therein, the fibre bend(s) disposed in a first section at or adjacent a first end of the optical fibre
25 sensor probe, the optical fibre probe having a second section adjacent the first section, and a third section adjacent the second section, and

(b) encapsulating the second section of the optical fibre sensor probe in potting compound and curing the
30 potting compound, ends of the optical fibre(s) extending from the second section and through the third section,

characterized in that said method further comprises the steps of:-

(c) emplacing a first tube over the third section of
35 the optical fibre sensor probe, and/or

(d) emplacing a second tube over the first section of the optical fibre sensor probe.

The present invention also provides a method for automatically potting one or more optical fibres, the
5 method comprising

disposing at least one optical fibre for application thereto of potting material,

applying potting material to the at least one optical fibre by moving a potting material pump along
10 the fibre, the pump applying potting material to at least one optical fibre as it moves therealong.

Further features of the invention are set out in Claims 2-18, 20 and 21.

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For a better understanding of the present invention and to show how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:-

5 Figure 1 shows the first step in the manufacture of one embodiment of an optical fibre sensor probe in accordance with the invention;

Figure 2 is a view taken on line II-II of Figure 1;

10 Figures 3 to 8 are side views showing six further steps in the manufacture of the optical fibre sensor probe;

Figure 9 is a top plan view showing the next step in the manufacture of the optical fibre sensor probe;

Figure 10 is a section on line X-X of Figure 9;

15 Figures 11, 12 and 13 show, to an enlarged scale, details of the sample chambers provided in the optical fibre sensor probe;

Figure 14 shows, to an enlarged scale, a detail of an alternative sample chamber;

20 Figure 15 shows a side view of a second embodiment of optical fibre sensor probe in accordance with the invention; and

Figure 16 shows a top plan view of the optical fibre sensor probe shown in Figure 15.

25 Referring to Figures 1 and 2 of the drawings, three optical fibres 1, 2 and 3 are suspended over vertically spaced mandrels 4 and 5 as shown.

30 Tension is then applied to the ends of the optical fibres 1, 2, 3, to maintain them in a substantially parallel array. Hot air is then blown onto the bends to aid in the formation of uniform and precise bends which conforms to the curvature of the mandrels 4, 5 and is made permanent by a thermoplastic set.

35 With the optical fibres 1, 2, 3 in position and held taut, a potting compound comprising a UV (ultravio-

let) curable adhesive is uniformly applied to a second section 7 of the optical fibres between a first section 6 and a third section 8 (Fig. 3). The potting compound is applied by a pump in a uniform vertical unidirectional pass and is cured by intense pulses of UV light generated by two sources of UV light which are disposed on either side of the optical fibres and which are moved vertically along the optical fibres.

An identification mark 9 is placed on the potting compound above the central optical fibre 2. The tension on the optical fibres 1, 2, 3 is then released and the formed body 10 (Fig. 3) is removed from the mandrels 4, 5.

The optical fibres 1, 2, 3 are preferably made from polymeric material whilst the preferred potting compound is ELC 4481 made by Electrolyte Corporation. It is preferred that the maximum diameter of the formed body 10 is kept at or below 600 μ m when optical fibres having a diameter of 125 μ m are used.

As shown in Figure 4 a thermocouple 11 having wires 12 is next positioned in the third section 8 of the formed body 10. The thermocouple 11 is a type T thermocouple with a lead diameter of 5×10^{-2} mm and a bead size of 0.2 mm respectively.

The loose strands of the optical fibres 1, 2 and 3, together with the leads 12, are passed through a first tube 13 (Figure 5) which is opaque, thin walled, smooth and flexible. A second adhesive (Epotak 301 from Epoxy Technology Co.) is then introduced into the first tube 13 to give the third section 8 increased structural strength. The extra strength is beneficial in a clinical situation when an optical probe sensor has to be inserted through a catheter, particularly one which is bent.

Prior to curing the second adhesive the distal end 14 of the tube 13 is pushed against the second section 7

and allowed to relax so that a tapered section 15 of adhesive is formed between the second section 7 and the third section 8.

5 The tube 13 is preferably black and is preferably made from polyamide material. For this particular device the outside diameter of the tube 13 is preferably about 500 μ m. The length of the tube 13 is preferably from 75 to 150mm. The relative decrease in diameter from the second section 7 to the third section 8 has significant
10 advantages in clinical applications. since it allows relatively free flow of fluids through the catheter.

The surface of the tapered section 15 is made good using the potting compound. This step is performed by the outward extrusion of the formed body through a
15 precision metal orifice filled with the potting compound. This step also adds potting material to the optical fibre in the first section 6 and may slightly increase the overall diameter of formed body. However, the surface finish is significantly improved. The bent
20 ends of the optical fibres 1, 2, 3 are thinly coated with potting compound which protects these from harsh solvents contained in subsequent coatings. After this step (Fig. 6) the maximum diameter of the formed body is about 650 μ m.

25 The first section 6 is then dipped vertically into a solvent based solution to uniformly coat the bent optical fibre portions with an opaque coating 16. The opaque coating 16 enhances optical insulation of the optical fibres both from external light and from adjacent optical fibres.
30

To further optically isolate and strengthen the first portion 6, a second tube 17 is bonded to the optical fibres 1, 2, 3 in the first section 6 using the potting compound. The second tube 17 is short (typically
35 about 2.5mm in length), opaque (preferably black) and

thin walled. It is preferably made from polyamide material. A smooth round tip 18 is formed at the end of the first section 6 remote from the second section 7.

Preferably, the outer diameter of the second tube
5 17 matches that of the second section 7.

At the proximal end 19 of the optical probe sensor, loose optical fibres 1, 2, 3 and the leads 12 from the thermocouple pass through a third tube which, in use, is used to manoeuvre the formed body 10 into position.

10 As shown in Figure 9, the next step is to cut sample chambers 20, 21 and 22 in the second section 7. The sample chambers 20, 21, 22 are cut using an excimer laser and extend through the optical fibres 2, 1 and 3 respectively as can be seen in Figure 10. Typically, the
15 sample chambers 20, 21, 22 are $150\mu\text{m} \times 150\mu\text{m} \times 100\mu\text{m}$ deep. The sample chambers 20, 21, 22 subtend an angle of approximately 140° with respect to the longitudinal axis of the formed body 10.

Each sample chamber 20, 21, 22 is then prepared.

20 Firstly, (Fig. 11) the sample chamber 21 is loaded with a pCO_2 indicator complex 23. Secondly, (Fig. 12) the sample chamber 20 is loaded with a pO_2 indicator complex 24.

A patch 25 comprising an O_2 permeable membrane is
25 then applied over the sample chamber 20.

A small amount of pCO_2 support media is then introduced into the sample chamber 21 to rehydrate the pCO_2 indicator complex 23.

A patch 26 comprising a CO_2 permeable membrane is
30 then applied over the sample chamber 21.

The patches 25 and 26 are then permitted to cure in a humid environment to gain structural strength and to effect proper bonding to the surface of the probe.

The first section 6 and the second section 7 are
35 then dipped to form a second coating 27 which is perme-

able to both CO_2 and O_2 . The second coating 27 is only applied up to a level just below the sensor chamber 22. The second coating 27 is then allowed to cure in a humid environment.

5 Sample chamber 22 (Fig. 13) is then loaded with a pH indicator complex 28. The filled sample chamber 22 is then covered with a patch 29 which, in this case, comprises a water permeable membrane.

10 The formed body 10 is then dipped to provide an opaque, water permeable membrane 30 which further optically isolates the optical fibres 1, 2, 3.

Finally, a thin uniform anti-thrombogenic coating 31 is applied to the whole.

15 Various modifications to the embodiment thus far described are envisaged. For example, as shown in Figure 14 the patch 29 may be replaced by a water permeable dip membrane 29'. Whereas the thermocouple 11 is shown in the third section 8 it could alternatively be provided in the first section 6. Such an embodiment is shown
20 in Figures 15 and 16 where similar parts to those in the preceding Figures have been identified by the same reference numerals with the addition of an apostrophe.

25 The preferred compositions of the pCO_2 indicator complex 23, the pO_2 indicator complex 24 and the pH indicator complex 28 together with the compositions of the various coatings is described in more detail in our PCT application PCT/EP93/ of even date.

30 Preferably, the pH indicator complex 28 comprises phenal red covalently bonded to the surface of porous glass and made into a slurry or gel with a hydrophobic polymer such as hydroxy ethyl cellulose.

35 Preferably, the pCO_2 indicator complex 23 comprises phenal red made into a gel with a hydrophilic polymer and having a desired concentration of bicarbonate to create carbonic acid inside the sample chamber 21 after

exposure to CO₂.

Preferably, the pO₂ indicator complex 24 comprises an oxygen quenchable or sensitive fluorescent indicator dye such as a Ruthenium II compound.

5 The anti-thrombogenic coating 31 preferably comprises a heparine complex of benzalkonium chloride.

 The gas permeable membrane preferably comprises a polydimethyl siloxane copolymer.

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Claims:

1. A method for making an optical fibre sensor probe, which method comprises the steps of:-

(a) taking one or more optical fibres (1,2,3) each
5 having a bend therein, the fibre bend(s) disposed in a first section (6) at or adjacent a first end of the optical fibre sensor probe, the optical fibre probe having a second section (7) adjacent the first section (6), and a third section (8) adjacent the second section,
10 and

(b) encapsulating the second section (7) of the optical fibre sensor probe in potting compound and curing the potting compound, ends of the optical fibre(s) (1,2, 3) extending from the second section (7) and through the
15 third section (8),

characterized in that said method further comprises the steps of:-

(c) emplacing a first tube (13) over the third section (8) of the optical fibre sensor probe, and/or
20 (d) emplacing a second tube (17) over the first section of the optical fibre sensor probe.

2. A method according to Claim 1, wherein said method comprises the step of emplacing a first tube (13) over the third section (8) of the optical fibre sensor probe, characterized in that the first tube (13) is opaque and flexible.
25

3. A method according to Claim 1 or 2, wherein said method comprises the step of emplacing a first tube (13) over the third section (8) of the optical fibre sensor probe, characterised in that said method further comprises the step of filling the first tube (13) with adhesive to strengthen the third section (8).
30

4. A method according to Claim 1, 2 or 3, wherein said method comprises the step of emplacing a first tube (13)
35 over the third section (8) of the optical fibre sensor

probe, characterized in that said method further comprises the step of, prior to emplacing the first tube (13), disposing a thermocouple (11) in the third section (8), the thermocouple (11) having thermocouple leads (12) extending from the third section (8).

5 5. A method according to any preceding Claim, wherein said method comprises the step of emplacing a first tube (13) over the third section (8) of the optical fibre sensor probe, characterized in that the first tube (13) comprises a polyamide.

6. A method according to any preceding Claim, characterised in that the second section (7) of the optical fibre sensor probe is larger in cross-section than the third section (8), the optical fibre sensor probe has a fourth section between the second section (7) and third section (8), and the fourth section tapers from the second section (7) to the third section (8).

7. A method according to any preceding Claim, wherein said method comprises the step of emplacing a second tube (17) over the first section (6) of the optical fibre sensor probe, characterized in that the second tube (17) comprises a polyamide.

8. A method according to any preceding Claim, wherein said method comprises the step of emplacing a second tube (17) over the first section (6) of the optical fibre sensor probe, characterised in that said method further comprises the step of bonding the second tube (17) to the first section (6) of the optical fibre probe.

9. A method according to any preceding Claim, wherein said method comprises the step of emplacing a second tube (17) over the first section (6) of the optical fibre sensor probe, characterised in that said method further comprises the step of, prior to emplacing the second tube (17), encapsulating the portions of optical

fibre(s) in the first section (6) in potting compound and curing the potting compound.

10. A method according to Claim 9, characterised in that it comprises the step of, prior to emplacing the
5 potting compound, applying an opaque coating (16) to the optical fibres (1,2,3) in the first section (6).

11. A method according to any preceding Claim, characterised in that it comprises the steps of forming a smooth round tip (18) of potting compound at the end of
10 the first section (6) remote from the second section (7), and curing the potting material.

12. A method according to any preceding Claim, characterised in that it further comprises the step of harnessing optical fibre ends extending from the third
15 section (8) of the optical fibre probe and a portion of the first tube (13) in a third tube for connection to an optical fibre connector.

13. A method according to any preceding Claim, wherein said plurality of optical fibres comprises three optical
20 fibres (1,2,3), each having a sample chamber (20,21,22) formed therein, characterised in that said method further comprises the steps of:-

installing a $p\text{CO}_2$ indicator complex (23) in a first sample chamber (22);

25 installing a $p\text{O}_2$ indicator complex (24) in a second sample chamber (21);

applying a curable O_2 permeable membrane over the $p\text{O}_2$ indicator complex;

30 applying a curable CO_2 permeable membrane over the $p\text{CO}_2$;

allowing the O_2 and CO_2 gas permeable membranes to cure,

applying a curable O_2 and CO_2 permeable membrane over both the $p\text{O}_2$ and the $p\text{CO}_2$ indicator complexes and

35 allowing it to cure;

installing a pH indicator in the third sample chamber (23), and

applying a liquid permeable membrane over the pH indicator complex.

5 14. A method according to Claim 13, characterised in that it includes the step of curing the permeable membranes in a humid environment.

15 15. A method according to any preceding Claim, characterised in that it further comprises the step of applying an opaque coating (30) to the first, second and third sections (6,7,8).

16. A method according to Claim 15, characterised in that it further comprises the step of applying a second opaque coating to the first, second and third sections (6,7,8).

17. A method according to any preceding Claim, characterised in that it further comprises the step of applying an anti-thrombogenic coating (31) to the first, second and third sections (6,7,8).

20 18. A method according to any preceding Claim, characterised in that it further comprises the step of prior to encapsulating the second section (7), disposing a thermocouple (11') in the first section (6'), the thermocouple (11') having thermocouple leads (12') extending
25 from the optical fibre probe.

* * *

19. A method for automatically potting one or more optical fibres, the method comprising

30 disposing at least one optical fibre for application thereto of potting material,

applying potting material to the at least one optical fibre by moving a potting material pump along
35 the fibre, the pump applying potting material to the at

least one optical fibre as it moves therealong.

20. A method according to Claim 19, characterized in that it further comprises the step of curing the potting material by moving a light along the fibres.

- 5 21. A method according to Claim 20, characterized in that the potting material comprises ultraviolet-light-curable potting material, and the light is an ultraviolet light.

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FIG. 1

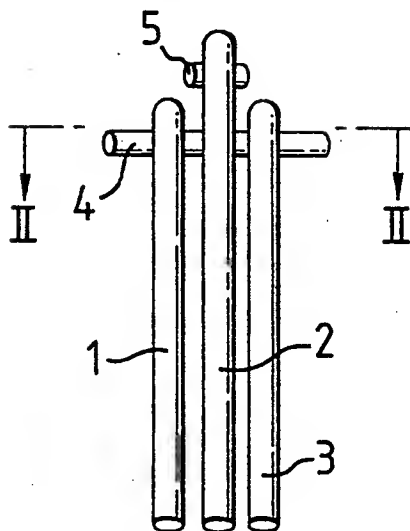


FIG. 2

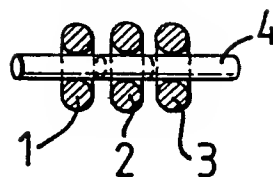


FIG. 3

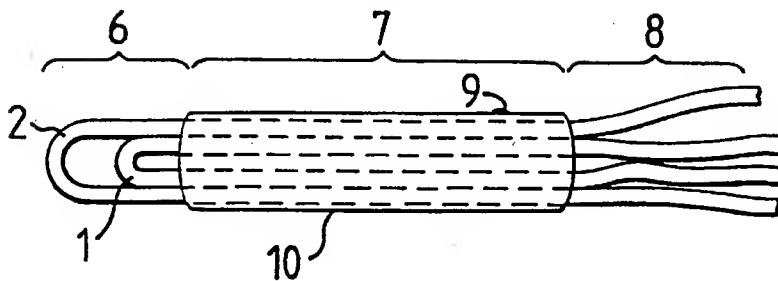
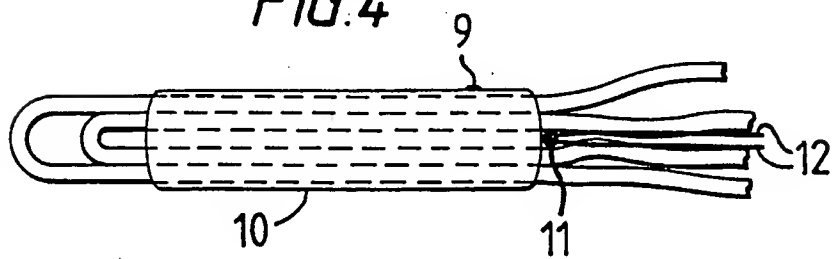


FIG. 4



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FIG. 5

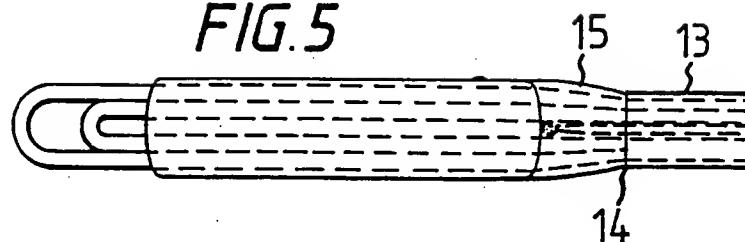


FIG. 6

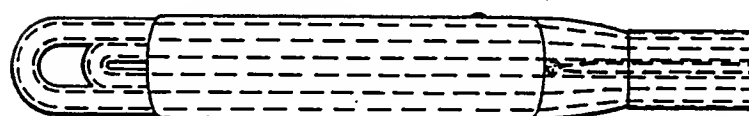


FIG. 7

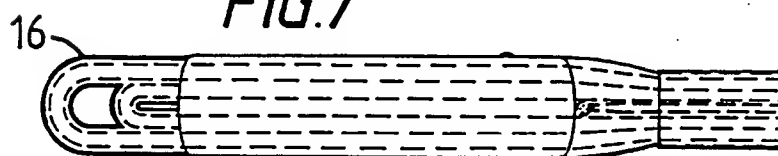


FIG. 8

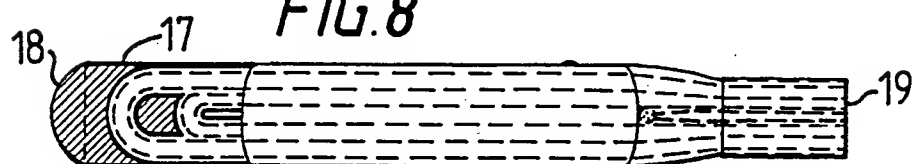
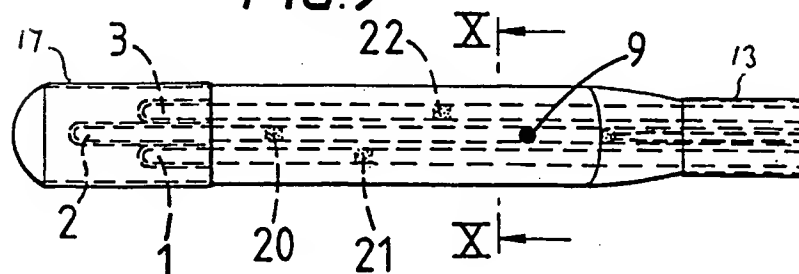


FIG. 9



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FIG. 15

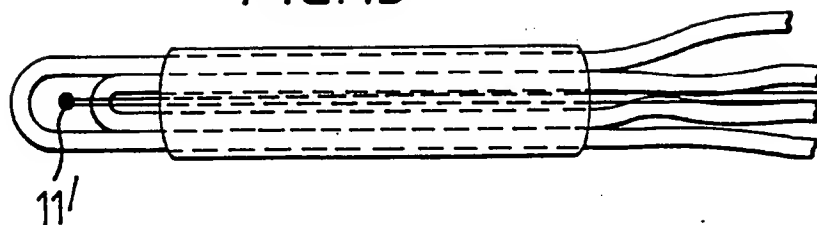
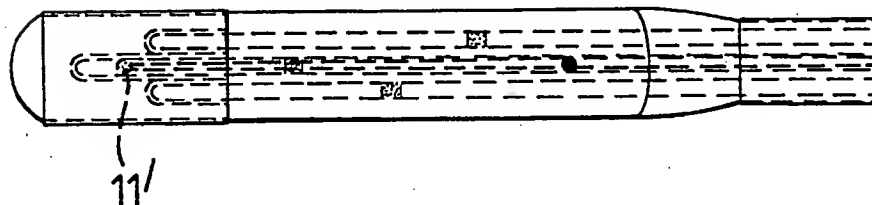
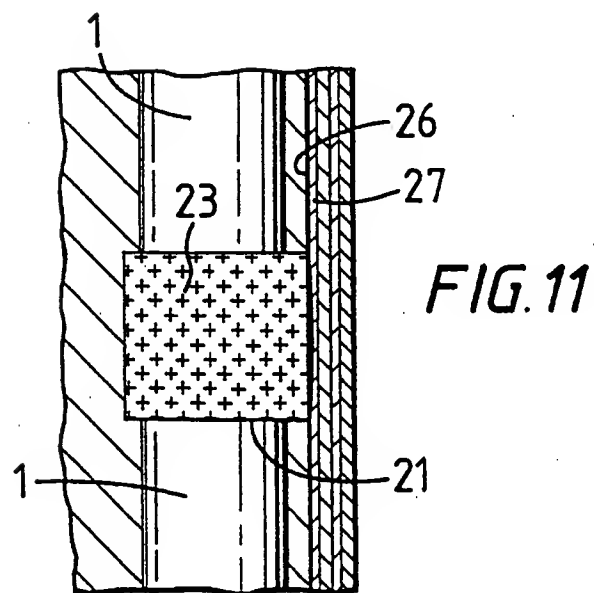
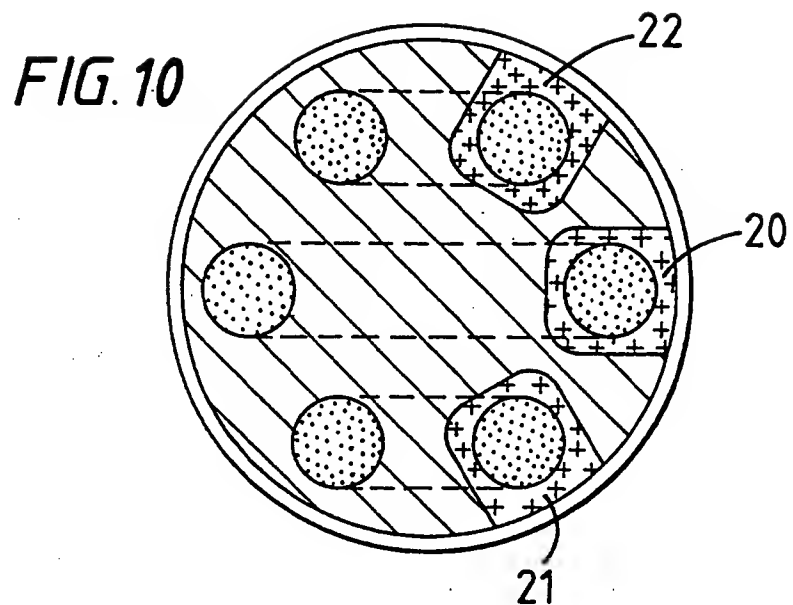


FIG. 16



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FIG. 12

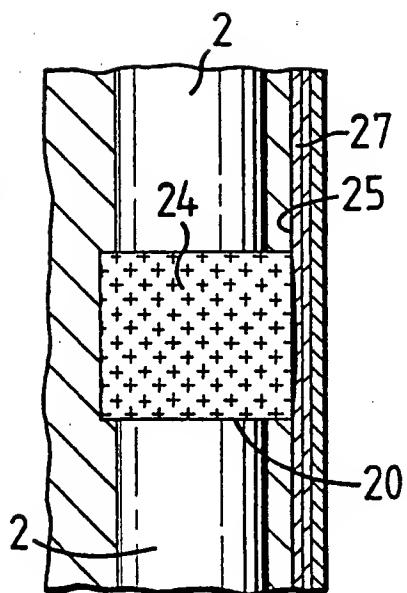


FIG. 13

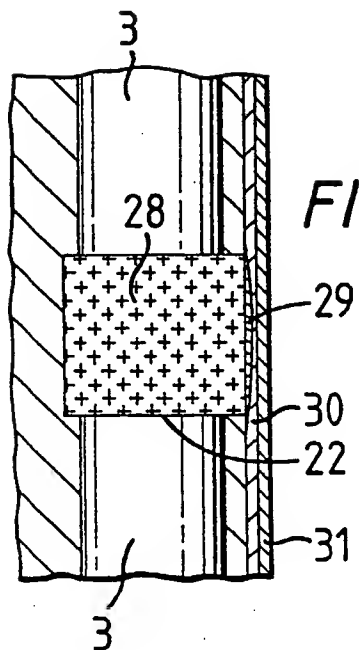
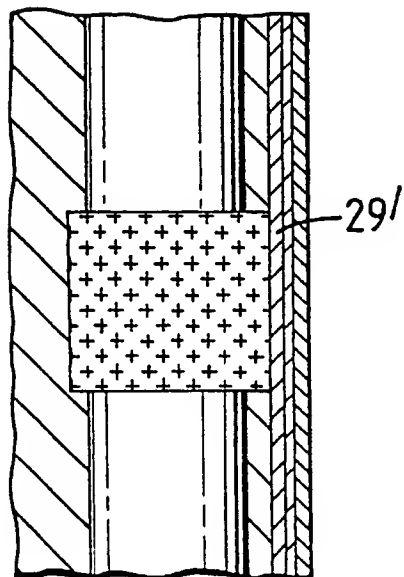


FIG. 14



INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP 93/02774

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims 1-18
 2. Claims 19-21
- For further information please see form PCT/ISA/206 mailed 02.02.94.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-18

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 93/02774

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-9118306	28-11-91	US-A- 5124130 AU-B- 645323 AU-A- 7889691 EP-A- 0530262	23-06-92 13-01-94 10-12-91 10-03-93
EP-A-0530262	10-03-93	US-A- 5124130 AU-B- 645323 AU-A- 7889691 WO-A- 9118306	23-06-92 13-01-94 10-12-91 28-11-91
EP-A-0279004	24-08-88	JP-A- 63212332 US-A- 4900381	05-09-88 13-02-90
WO-A-8700920	12-02-87	US-A- 4682895 CA-A- 1292665 EP-A, B 0232369 JP-T- 63500737	28-07-87 03-12-91 19-08-87 17-03-88
EP-A-0232369	19-08-87	US-A- 4682895 CA-A- 1292665 JP-T- 63500737 WO-A- 8700920	28-07-87 03-12-91 17-03-88 12-02-87
US-A-5047627	10-09-91	AU-B- 646462 AU-A- 7714191 CA-A- 2042794 EP-A- 0457292 JP-A- 4231850	24-02-94 21-11-91 19-11-91 21-11-91 20-08-92

INTERNATIONAL SEARCH REPORT

 Internat Application No
 PCT/EP 93/02774

 A. CLASSIFICATION OF SUBJECT MATTER
 IPC 5 G01N21/77

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 5 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO-A-91 18306 (OPTEX BIOMEDICAL) 28 November 1991 see page 7, line 10 - page 9, line 10 see page 12, line 16 - page 14, line 2 see page 19, line 14 - line 20 see claims 34,40; figures 1-4,12-14	1,9,13, 18
D,Y	& EP-A-0 530 262 (OPTEX BIOMEDICAL)	1,9,13, 18
Y	EP-A-0 279 004 (HEWLETT-PACKARD) 24 August 1988 see column 6, line 21 - line 58; figure 5	1,9,13, 18
A	WO-A-87 00920 (OPTEX BIOMEDICAL) 12 February 1987 see abstract; figures 1,2	1
D,A	& EP-A-0 232 369 (OPTEX BIOMEDICAL)	1
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☒ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search

12 January 1994

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/LP 93/02774

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US-A-5 047 627 (YIM ET AL.) 10 September 1991 see abstract; figures -----</p>	1